

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY

*Original*

01/14/2004

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*04-182(SRC)*

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U.S. DISTRICT COURT  
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Dr. George Piczenik

Plaintiff

v.

Merck & Co., Inc.,

Defendants

*15 2004*

COMPLAINT FOR PATENT INFRINGEMENT AND RACKETEER  
INFLUENCE & CORRUPT ORGANIZATION (RICO) AND JURY  
DEMAND

For its complaint herein, Plaintiff alleges as follows:

THE PARTIES:

- 1) Plaintiff, George Piczenik ("Piczenik") is a New York resident residing at 412 East 55<sup>th</sup> st. Apt. 1F, New York, N.Y. 10022.
- 2) Defendant, Merck & Co., Inc. ("Merck") is a New Jersey corporation located at One Merck Drive, P.O. Box 100, Whitehouse Station, N.J. 08889-0100.
- 3) Merck is involved in manufacturing, re-manufacturing, research, licensing agreements, patent applications, and patents in areas encompassed by the Piczenik patents '363 and '448 and filed after the 102(c) date of the Piczenik patents.
- 4) Plaintiff has given prior written noticed to Merck of their said infringement when Plaintiff served a Summons and Complaint for

Infringement.

### I. JURISDICTION AND VENUE

- 5) This action arises under the patent laws of the United States of America and Jurisdiction is founded on Title 28, United States Code § 1331 and 1338 (a). Venue is proper in this Court under Title 28, United States Code § 1391 (c)(d)(e1) and 1400(b)
- 6) On August 12, 2003 the United States Patent Office issued Patent No. 6,605,448 B1 ('448) were duly and legally issued to Plaintiff for an invention entitled "Method and Means for Sorting and Identifying Biological Information"; and since that date Plaintiff has been and still is the owner of those Letters Patent. This patent grants plaintiff rights to exclude others from making and owning intermediate and end products of libraries of displayed peptides and test species and antibodies that interact with these libraries. This patent has an effective 102 (e ) priority date of August 28, 1985.
- 7) On February 2, 1999 the United States Patent Office issued United States Letters Patent No. 5, 866, 363 ('363) were duly and legally issued to Plaintiff for an invention for entitled "Method and Means for Sorting and Identifying Biological Information. This 363 patent is the parent of the '448 patent and also has an effective 102(e) priority date of August 28, 1985. Plaintiff is the owner of the '448 and the '363 patents. This patent grants plaintiff rights to exclude others from making and owning intermediate and end products of libraries of displayed peptides and test species and antibodies that interact with these libraries.
- 8) On November 16, 1982 the United States Patent Office issued United States Letters Patent No. 4,359,535 ('535) were duly and

legally issued to Plaintiff for an invention for entitled "Autonomously Replicating DNA Containing Inserted DNA Sequences". This patent grants plaintiff rights to exclude others from making and owning intermediate and end products of DNA sequences amplified and re-manufactured and sequenced with single stranded DNA vectors and templates.

- 9) On July 9, 1985 the United States Patent Office issued United States Letters Patent No. 4,528,266 ('266) were duly and legally issued to Plaintiff for an invention for entitled "Method of Inserting Unique DNA Sequences into DNA Vectors". This patent grants plaintiff rights to exclude others from making and owning intermediate and end products of DNA sequences amplified and re-manufactured and sequenced with single stranded DNA vectors and templates and inserted with blunt end ligation.

- 10) This Court has jurisdiction over this action pursuant to 12 U.S.C. §1819, 18 U.S.C. §1964, and 28 U.S.C. §1349.

- 11) Venue is proper in this judicial district pursuant to 28 U.S.C. §1391(b)(2) in that the claims stated herein arose in this district.

- 12) This Court has jurisdiction pursuant to 35 USC § 290 and/or 15 USC § 1116 and which fall under 37 CFR 1.501, 37 CFR 1.502, 37 CFR 1.525, 37 CFR 1.510, 37 CFR 1.535, 37 CFR 1.510, and 35 USC 102(e).

- 13) Venue is proper in this Court under Title 28, United States Code § 1391 (c)(d)(e1) and 1400(b)

## II. CLAIM

- 14) Pieczenik is the owner and inventor of the United States Patent No.

6,605,448 B1 ("the '448 Patent"), which discloses and claims a method and means of identifying biological information.

15) Pieczenik is the owner and inventor of the United States Patent No. 5,866,363 ("the '363 Patent"), which discloses and claims a method and means of identifying biological information.

16) Pieczenik is the owner and inventor of the United States Patent No. 4,359,535 ("the '535 Patent"), which discloses and claims single stranded DNA vectors for sequencing and expression.

17) Pieczenik is the owner and inventor of the United States Patent No. 4,528,266 ("the '266 Patent"), which discloses and claims single stranded DNA vectors for sequencing and expression and methods of sequencing and expression with random blunt end insertions.

18) On information and belief Merck uses and has filed patents claiming methods and biological intermediates used in the display of peptides and antibodies libraries on the surface of bacteriophage fl, fd, M13 and chemical matrices. These patents and patent applications have been filed at a later date than the original filing of the Pieczenik '363 and '448 patents. Therefore, the defendant's patents are now subject to a 102(e) "snap back" prior art date. Because this '448 patent has now issued and the '363 previously; and as, defendant's patents contain claims defendant's patents and patent filings must be modified by an IDS filing informing the USPTO of this Pieczenik prior art.

19) On information and belief Merck has acquired VWR International ("VWR") and VWR is a fully owned subsidiary of Merck

20) On information and belief VWR has an American Corporate Headquarters at 1310 Goshen Parkway, West Chester, PA 19380

- 21) On information and belief Merck and/or its acquired companies VWR have purchased combinatorial libraries from New England Biolabs and by their use, purchase, remanufacturing, distribution and sale infringe the '363, '448, '535 and '266 Picczenik patents.
- 22) On information and belief, Defendant Merck licenses rights under its patents in New Jersey, the United States and the world.
- 23) On information and belief, by virtue of defendant's manufacturing, re-manufacturing, research, collaborations, commercial licensing and distribution agreements with VWR, defendant has infringed upon plaintiff's patents and has contributed and induced others to infringe Plaintiff's patents.
- 24) On information and belief, to the extent that the claims in defendant's patents relating to the phage display of combinatorial libraries and single stranded DNA sequencing vectors are substantially similar to claims in plaintiff's patent, defendant's patents are invalid.
- 25) On information and belief, the defendant's patents and new applications now fall under a 35 USC 102(e) "snap back" provisions of patent law. This is the patent equivalent of a *nunc pro tunc* order by the USPTO back to 1985 when the '363 and the '448 were filed. That is the newly issued patents that took over 18 years to issue have to be considered now as if then when they were filed in terms of all patents in this area. While, the Commissioner of Patents has the authority to re exam all the defendant's patents cited in this litigation in terms of the specifications and claims of Plaintiff's patents as new prior art *nunc pro tunc* 1985, the Commissioner of Patents requires all inventors, assignees, IP lawyers and anyone in the chain to inform the USPTO of any new patents at issue that impact on their

previously issued patents.

- 26) On information and belief, the Doctrine of Patent Exhaustion does not apply to the sale of re-manufactured recombinant libraries, plain or combinatorial, using single stranded vectors such as are sold by VWR and which infringe the '363, '448, '535 and '266 Pieczenik patents.

### III. PRELIMINARY ALLEGATIONS

#### i. Count I – Patent Infringement and Inducement to Infringe

- 27) On information and belief, Merck has filed five patent applications, *inter alia*, which describe the use of combinatorial libraries and the use of DNA vectors containing such libraries. They are US 20020138862, US20030216290, US20030217379, US20030219451, *inter alia*. These aspects of these libraries are subsumed by the Pieczenik '363 and '448 patents. Since Merck is also not an eleemosynary corporation, it is reasonable to suggest that these patent applications represent a commercial interest and active research program in methods and products claimed in '363 and '448. One example, *inter alia*, is given below:

- a. An example of the practice of the method in this manner would be the screening of a library of compounds, e.g., a **combinatorial** library, against the enzymatically active preparation of PTP-1B. In such cases, typically only a small fraction of the substances in the library will be found to be inhibitors of the enzymatic activity of PTP-1B. If the library is large, it may be divided into conveniently small portions of substances for use in step (b). This embodiment reads directly on the claims of the '363 and the '448 patents.

- 28) On information and belief VWR has licensing, collaborations,

manufacturing, sales and distribution with Merck. VWR makes, re-makes, sells and licenses combinatorial libraries and sequencing vectors which infringe Pieczenik's patents.

- 29) On information and belief Merck's and VWRs collaboration, commercialization, FDA filings and/or other relationships infringe Pieczenik's patents.
- 30) On information and belief, Merck's sponsoring of meetings involving combinatorial libraries and single stranded sequencing vectors such as the COMBINATORIAL APPROACHES TO CHEMISTRY AND BIOLOGY meeting organised by The Perkin Division of the Royal Society of Chemistry and the RSC Industrial Affairs Division, Biological and Medicinal Chemistry Sector, on July 27-31, 1997, at Churchill College, Cambridge, U.K, *inter alia*, induce to infringes Pieczenik's patents. Companies such as Amgen, Affymax, Smith Kline Beecham, and Glaxo, inter alia, were so induced by this sponsorship.
- 31) On information and belief, Merck's collaboration, commercialization, FDA filings, and/or other relationships with Dyax, infringes Pieczenik's patents. Dyax makes, sells and licenses combinatorial libraries which infringe and induce to infringe Pieczenik patents.
- 32) On information and belief, Merck's scientific director Dr. Peter S. Kim infringes the Pieczenik's patents and Merck's licensing and agreements with the Whitehead Institute, Cambridge, Mass.
- 33) On information and belief, Merck's scientific director Dr. Peter S. Kim infringes the Pieczenik's patents.
- 34) On information and belief, Merck's licensing agreements and

collaborations with the Whitehead Institute, Cambridge, Mass.  
Infringe the Pieczenik patents.

- 35) On information and belief Merck and/or its acquired companies VWR, *inter alia*, and collaborators have purchased combinatorial libraries from New England Biolabs and by their use, purchase and remanufacturing infringe the '363 and '448 Pieczenik patents.
- 36) On information and belief, by virtue of defendant's manufacturing, re-manufacturing, research, collaborations, commercial and licensing agreements defendant has infringed upon plaintiff's patent and has contributed and induced others to infringe Plaintiff's patents.
- 37) On information and belief, to the extent that the claims in defendant's patents relating to the phage display of combinatorial libraries are substantially similar to claims in plaintiff's patent, defendant's patents are invalid.

#### Count II (RICO)

- 38) This Count pleads a violation of the Racketeer Influenced and Corrupt organization Act (18 U.S.C. §1961 et seq.). specifically, this Count alleges a violation of 18U.S.C. §1962(b) in that the defendants, through a pattern of racketeering activity, sought to acquire or maintain, directly or indirectly, an interest or control in the enterprise, the activities of which affect interstate or foreign commerce.
- 39) This Count also alleges a violation of 18 U.S.C. §1962(c) in that the defendant, who is employed by or associated with the enterprise, conducted the affairs of that enterprise through a pattern of racketeering.



- 40) This Count also alleges a violation of 18 U.S.C. §1962(d) in that the defendant conspired to violate subsections (b) and (c) of 18 U.S.C. §1962(d).
- 41) The racketeering predicate acts which are alleged herein, all which occurred within the last ten years, consisted of mail fraud within the meaning of 18 U.S.C. §1941 and wire fraud within the meaning of 18 U.S.C. §1943.
- 42) This Count also alleges that "by reason of" the violations of 18 U.S.C. §1962, plaintiff has been damaged.
- 43) While more fully described below, said unlawful scheme and conspiracy engaged in by the defendant may be summarized as follows: The defendant sought to impose unnecessary financial burdens on the public and the Plaintiff by collaborating with Dyax Corp. thereby encouraging the public to purchase their shares of stock at drastically inflated and commercially unreasonable prices and limiting Plaintiff's access to financing by defendants anti-trust behavior.
- 44) To the extent that communications were had with potential investors over telephone numbers 908 423-1000 Merck, 617 225-2500 Dyax the foregoing also constituted wire fraud within the meaning of 18 U.S.C. §1343.
- 45) By reason of the aforesaid intentional manipulation of the value of the respective biotech stocks of the enterprise and racketeering activities of the defendant's collaborators, in order to "pump and dump", after collaboration announcements with defendant, shares of stock, the patents owned by the Plaintiff has been rendered unmarketable, not licensable and, therefore, relatively worthless in

respect to their true value.

- 46) On information and belief, a fair value of the Picczenik patents, by the independent Analysis Group/Economic for Merck's infringement is in the magnitude of \$68 million per year royalty.

PRAYER FOR RELIEF

Wherefore Plaintiff demands a preliminary and final injunction against continued infringement, an accounting for damages, and an assessment of interest and costs against the Defendant; and

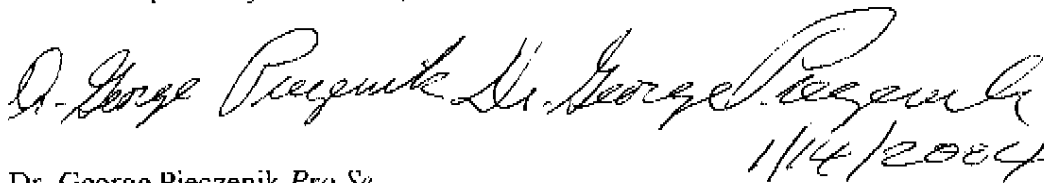
- 47) Judgment be entered that Defendant that Merck has infringed and is infringing the '366, '488, '535, and the '266 patents.
- 48) A preliminary and final injunction be issued pursuant to 35 USC 271 (e)(4)(B) restraining and enjoining said defendant, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, re-manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any products produced according to defendant's patents, or to license defendant's patents anywhere in the world or inducing to infringe the '363 and '448 patents and to continue collaborations with VWR and Dyax *inter alia*.
- 49) Damages for past and present willful infringement and treble damages;
- 50) Damages for the intentional devaluation of the Picczenik patents by Merck's collaboration with VWR and Dyax, *inter alia*.

51) Plaintiff demands a trial by jury.

52) A judgment be entered for damages against Merck and Merck's IP lawyers for failing to file re examinations or re issues on all patent and patent applications as of 1985 informing the USPTO of the prior art under the 35 USC 102(e) effective filing date as a consequence of the recent issuing of the Pieczenik patents after over 18 years in the USPTO.

53) For such other and further relief as the Court may deem proper under the circumstances.

Respectfully Submitted,

1/14/2004

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January 14, 2004,

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